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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 759,748	01 12 2001	David L. Benson	P04809US0 P11 1322	4873

27310 7590 05 19 2003

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05 19 2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/759,748

Applicant(s)

BENSON, DAVID L.

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7 and 20 is/are allowed.
- 6) ☒ Claim(s) 6, 8-19 and 21-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1638

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claims 6, 12, 16, 25, and 29 is withdrawn in light of the claim amendments.
3. The rejection of claims 1-32 under the judicially created doctrine of obviousness-type double patenting is withdrawn in light of the claim amendments.
4. The rejection of claims 1-32 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, for requiring a deposit of the claimed seed of hybrid corn line 33R77, is withdrawn, in light of the assurance by Applicant that said seed will be deposited upon notification of allowable subject matter (response submitted 03 October 2002, paragraph bridging pages 17-18), and the deposit statement on page 49 of the specification.

### ***Specification***

5. The specification remains objected to for containing blank lines on page 7. Applicant asserts, in the paper received 03 October 2002, that the ATCC deposit of seed 33R77 will occur when a notice of allowable subject matter is issued (response, page 9, 2<sup>nd</sup> full paragraph).

Art Unit: 1638

However, the blank lines on page 7 appear in place of missing accession numbers for the inbred parents of 33R77, not 33R77 itself.

***Claim Rejections - 35 USC § 112***

6. Claims 6, 8, 11, 12-15, 19, 21, 24-28, 32 remain and claims 33-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 03 July 2002 under item 4. Applicant traverses the rejection in the paper filed 03 October 2002. Applicant's arguments were fully considered but were not found fully persuasive. The amendments to claims 10, 14, 18, 23, 27, and 31 have overcome the aspect of the rejection regarding improper antecedent basis, and Applicant's assurance that the ATCC deposit number will be inserted into the claims upon notice of allowable subject matter overcomes the rejection regarding the term "33R77" for claims 1-32.

Regarding the indefinite issue concerning the relative terms in claims 11, 15, 19, 24, 28, and 32: Applicant argues that each of the claims recites two requirements: that 33R77 be an ancestor of the plant, and that the claimed plant be "capable of expressing a combination of at least two 33R77 traits" selected from a Markush grouping (response, paragraph bridging pages 11-12). However, this issue was not raised in this rejection. Applicant also argues that the terminology of the adjectives is well known in the art and would be understood by one skilled in the art. Applicant also argues that it is against the policy of the patent statutes to bar patent protection for inventions that are incapable of precise definition, and assert that the terms in the claims are as precise as the subject matter of the invention permits (response, paragraph bridging

Art Unit: 1638

pages 12-13). However, it remains unclear how one would differentiate, for example, "high" grain yield from "excellent" or "very good" yield. It is not clear if a plant that has high grain yield and excellent grain yield for its maturity, for example, would be encompassed by the claims.

In claim 6: there is improper antecedent basis for "protoplasts" in line 1.

In claims 8 and 21: the recitation "has been manipulated to be male sterile" renders the claims indefinite. It is not clear if the claim is directed towards detasseled plants, or plants that have been transformed with a gene conferring male sterility. The following amendments are suggested: 1) in claims 8 and 21, replace "manipulated to be male sterile" with --detasseled--; 2) add a new claim 44 directed towards a method of producing a transgenic male sterile maize plant comprising transforming the maize plant of claim 2 or 20 with a transgene that confers male sterility, and a new claim 45 directed towards a transgenic male-sterile maize plant produced by the method of claim 44.

In claims 11, 15, 19, 24, 28, 40, and 41: the recitation "deriving at least 50% of its ancestral alleles" renders the claims indefinite. It is not exactly clear what "deriving" alleles means.

In claims 12 and 25: the claims are indefinite because they broaden the scope of the claims from which they depend. Claims 2 and 20 do not encompass plants that contain transgenes.

In claims 34, 36 and 39: the recitation "33R77" renders the claims, and those dependent thereon, indefinite. Regarding indefiniteness of the term "33R77," Applicant argues that one ordinarily skilled in the art would understand that this designation is drawn to a new and distinct

Art Unit: 1638

hybrid maize seed with the designation of 33R77 and the morphological and physiological traits that are disclosed in the specification. Applicant asserts that the use of such a designation is common practice with the art (response, page 12, 2<sup>nd</sup> full paragraph). However, the morphological and physiological traits listed in the specification for seed 33R77 do not cover all of the traits of this plant line. For example, Table 1 does not report the resistance of 33R77 to many diseases and insects. If a corn plant displays all of the morphological and physiological traits as those reported for 33R77, but also displays a disease rating of 9 against southern rust, for example, can such a corn plant still be referred to as “33R77?” Further, the designation can be changed. Amending claims 34, 36 and 39 to indicate that seed of 33R77 was deposited under ATCC Accession No. \_\_\_\_\_ will overcome the rejection.

New claims 33 and 34 refer to two other corn lines, “GE515419 and GE567914.” No morphological and physiological descriptions are provided at all for these two lines, and it is not clear what plants are referred to by these designations.

In claim 36: the recitation “desirable morphological and physiological traits” in line 6 renders the claim indefinite. It is not clear what traits are considered desirable versus undesirable.

In claim 37: the claim recites the recitation “the pedigree” in lines 1-2. There is insufficient antecedent basis in the claim and the claim from which it depends for this limitation.

In claim 40: the recitation “said population, on average, deriving at least 50% of its ancestral alleles” in line 2 renders the claim indefinite. It is not clear whether or not the all of the claimed plants have at least 50% of the ancestral alleles from 33R77. The metes and bounds of the claim are not clear.

Art Unit: 1638

In claim 42: the recitation "further comprising applying double haploid methods" renders the claim indefinite. The recitation broadens the scope of parent claim 39, which only involves crosses and does not encompass any double haploid method. It is also not clear what double haploid method is being referred to.

In claim 43: the recitation "a second plant" in line 9 renders the claim indefinite. It is not clear if this second plant is different from or the same as the "second plant" mentioned in line 6.

7. Claims 11-19, 24-32 remain and claims 9, 10, 22, 23, 33-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reason of record stated in the Office action mailed 03 July 2002 under item 5. Applicant traverses the rejection in the paper filed 03 October 2002. Applicant's arguments were fully considered but were not found fully persuasive.

Applicant argues that the claim amendments overcome the rejection for claims 8 and 21 (response, page 14, 1<sup>st</sup> full paragraph). The amendments overcome the written description issue raised for these claims, and the rejection is withdrawn from claims 8 and 21.

Applicant argues that the claims have been amended by adding the threshold, having 50% of the ancestral alleles that limits the variation permitted among the genus, as well as an assayable function, capable of expressing a combination of at least two traits of 33R77. Applicant argues that in plants, identifying characteristics are those detectable in the phenotype, which are manifested through gene expression, and that claims to a particular species of

Art Unit: 1638

invention are adequately described if the disclosure of relevant identifying characteristics are present in the application. Applicant argues that one of ordinary skill is reasonably apprised in knowing that a plant crossed with 33R77 will result in a plant having half the genetic contribution of 33R77, and that a further limitation set is that the plants must be capable of expressing a combination of at least two phenotypic characteristics of 33R77 (response, page 15, 1<sup>st</sup> full paragraph). However, the specification does not provide a description of the alleles of 33R77, nor does it describe the functions that are associated with each of the alleles of 33R77. The specification does not describe the alleles that govern the expression of any of the traits enumerated in the claims. As the alleles of 33R77 are not described, neither are the alleles of its descendents. Further, new claims 37, 40, and 41 encompass plants that can express any traits, none of which are described.

Applicant also argues that the specification supplies an extensive definition and description of "transgene" and transgenes of interest. Applicant argues that the trivial modification introduced by the transgenes to 33R77 are clearly supported and described in the present application (response, page 16, 1<sup>st</sup> full paragraph to the paragraph bridging pages 16-17). However, as written, the claims encompass any and all transgenes, even those that have yet to be isolated. Further, the effect that a transgene can have on its host plant depends on the function of its encoded product, among other considerations, and the modification cannot simply be described as "trivial." A transgene that is a transcription factor, for example, could effect the expression of numerous genes and phenotypes. It is suggested that claims 12 and 25 be amended by listing the types of transgenes that may be introduced, provided that the specification or the



Art Unit: 1638

prior art indicates that the gene has been isolated, for example genes that confer resistance to a plant virus.

Further, the specification does not provide any description of a method of making inbred plants "GE515419 and "GE567914" from 33R77 and for double haploid breeding and other double haploid methods. Claims 34, 35, and 42 recite new matter. The specification at page 7 indicates crossing proprietary inbred plants GE515419 and GE567914 produced plant 33R77, but makes no mention of producing these same inbreds from 33R77. The specification does not provide any description of these inbred plants at all.

8. Claims 33-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a method of making a hybrid plant designated 33R77 comprising crossing inbred maize plants GE515419 and GE567914; a method of making inbred plant GE515419 or GE567914 from hybrid maize plant 33R77.

The specification indicates that proprietary Pioneer Hi-Bred inbred lines GE515419 and GE567914 were crossed to produce hybrid 33R77 (page 7, last paragraph).

However, the specification does not indicate that seeds of the inbred parents of 33R77 are available to the public, as they are proprietary lines. Lines GE515419 and GE567914 are essential to the practice of claims 33-35.

Art Unit: 1638

Since the lines GE515419 and GE567914 is essential to the claimed invention, their seeds must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public.

If the seeds are deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

Art Unit: 1638

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

9. Claims 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a method of making an inbred plant comprising obtaining a hybrid maize plant 33R77 and generating from said plant a parental inbred parent line selected from the group consisting of GE515419 and GE567914; or wherein said generating step comprises using double-haploid breeding.

The specification provides a general discussion on plant breeding, and asserts that the objective of commercial maize hybrid line development is to develop new inbred lines to produce hybrids that combine to produce high grain yields and superior agronomic performance (pages 3-7). However, the specification does not teach that hybrid maize plant 33R77 is to be used to produce its own inbred parents. The specification does not provide any guidance concerning how one skilled in the art is to practice the claimed method, even by using double haploid breeding. This method of producing inbred lines from hybrid plant varieties does not allow one to pick out the alleles that would be present in the resulting inbred line. Snape, J.W. (Doubled haploid breeding: theoretical basis and practical applications, In Review of Advances in Plant Biotechnology, 1989, A. Mujeeb-Kazi and L.A. Sitch, editors, International Maize and

Art Unit: 1638

Wheat Improvement Center, Mexico, pages 19-29), for example, teaches that a completely random sample of gametes is fixed in this method, and that large populations of doubled haploid lines would be required to identify lines advancing even a single character (pages 23-24). Undue experimentation would clearly be required by one skilled in the art to produce a line comprising particular alleles at each and every locus. Further, the specification does not teach anything about the alleles of GE55419 or GE567914, or any of their molecular, morphological, and physiological characteristics. In the absence of this information, one skilled in the art would not even know how to identify these two lines. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

10. Claims 11, 15, 19, 24, 28, 40, and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards maize plants or its parts wherein at least one ancestor is 33R77, and has derived at least 50% of its ancestral alleles from 33R77 and is capable of expressing a combination of at least two 33R77 traits listed in those claims; or wherein the maize plant is derived from 33R77 transformed with one or more transgenes or 33R77 contains one or more genes transferred by backcrossing; or a population of 33R77 progeny hybrid maize plants, said population, on average, deriving at least 50% of its ancestral alleles from 33R77 and expressing any traits.

Art Unit: 1638

The specification teaches morphological and physiological characteristics of maize plant 33R77 (pages 17-35).

However, the specification does not teach how one may determine that a descendent of 33R77, that expresses at least 2 of the traits listed in claim 11 for example, or any traits, could determine that at least 50% of its alleles were derived from 33R77, if any of its other ancestors also expressed those traits. The specification does not teach any determinants, such as molecular markers, that are unique to 33R77 and linked to the alleles that govern the traits, that one skilled in the art would need in order to determine that the traits could only have been derived from 33R77. Further, the specification does not teach the genes that govern the traits. It is not clear how one can determine that the traits could only have been derived from 33R77, or how one can distinguish 33R77 alleles versus those of other corn plants, if the specification does not teach the genes that govern the expression of those traits and unique molecular determinants associated with them, so that one can determine that it was inherited from 33R77. If other ancestors of the claimed plant also expressed the traits, then the genes governing the traits could have been inherited from that ancestor(s). If one does not know if a corn plant has 33R77 as an ancestor, and if unique molecular determinants that can identify genomic nucleic acid of 33R77 are unknown, undue experimentation would be required by one skilled in the art to alleles derived from 33R77. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Given the breadth of the claim, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

***Claim Rejections - 35 USC § 102 & 103***

11. Claims 11, 15, 19, 24, 28, 32 remain and claims 37, 40, and 41 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Whitaker (U.S. Patent No. 6,107,551).

Applicant points out several differences between hybrids 33R77 and 33Y11, such as in anther color and silk color, among others (response, page 19, 1<sup>st</sup> full paragraph; pages 21-22). This argument is found sufficient to overcome the rejection for claims 1-10, 12-14, 16-18, 20-23, 25-27, and 29-31.

Applicant argues that the claims do not simply recite traits, but rather specific traits only to the extent that they are "33R77" traits, being derived from the seed/germplasm of 33R77. Applicant argues in response to the Examiner's contention that one could not distinguish the claimed plant from prior art which shows each of these traits, that one can easily tell by reference to the plant's breeding history, which can be confirmed by its molecular profile whether the plant has 33R77 as an ancestor and expressed two or more "33R77" traits (response, paragraph bridging pages 19-20). However, Applicant does not teach the molecular profile of 33R77. Applicants have only described 33R77 by the traits it expresses. The Examiner does not have sufficient facts to determine if the prior art plants have the same molecular profile as 33R77.

Applicant argues that it is the combination of physiological and morphological characteristics, as claimed, which make the present hybrid non-obvious and not anticipated. Applicant argues that the plant of Whitaker is not the same plant as can be evidenced by analysis

Art Unit: 1638

of the data tables (response, page 20, 1<sup>st</sup> full paragraph). However, the claims only recite that the plant need only express two 33R77 traits, which 33Y11 does, not all of the traits.

While the combination of genes in the genome of 33R77 may be unique, the specification does not teach that any particular gene is unique. Molecular markers that are unique to the 33R77 genome and which are associated with the traits listed in the claims are not taught. One cannot determine the differences in the instantly claimed plants from those of the prior art based on an analysis of the genome. Some of the claims only require that 2 of the listed traits be expressed, and other claims do not place any limitation on the traits at all. Prior art plants having the same characteristics as the instantly claimed plants would anticipate the claimed plants even if made by different methods (i.e. different parent plants), and in the present case, not all of the claims place limitations on the characteristics that can be expressed. The Examiner does not have sufficient facts to determine whether the progeny plants and seeds are inherently the same. The Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the plants differ from teachings of the reference. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

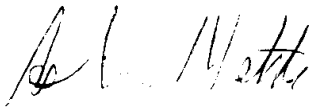
12. Claims 1-5, 7 and 20 are allowed. Claims 6, 8-19 and 21-43 are rejected.

Art Unit: 1638

***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

May 14, 2003

  
**ASHWIN D. MEHTA, PH.D**  
**PATENT EXAMINER**